



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,692	10/31/2005	Sabaratham Sabanathan	017534-005600US	7840
20350 7590 08/19/2009 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834				
EXAMINER				
SHOME, ARUNDIPTA				
ART UNIT		PAPER NUMBER		
3771				
MAIL DATE		DELIVERY MODE		
08/19/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/762,692

Applicant(s)

SABANATHAN ET AL.

Examiner

ARUNDIPTA SHOME

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-39, 41 and 49-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-39, 41 and 49-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 27-39, 41, and 49-51 are pending. This Action is in response to the amendment filed 7-13-2009.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7-13-2009 has been entered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 27-39, 41, and 49-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5. Regarding Claims 27 and 49, the originally filed disclosure does not include the newly added limitation "inserting a blocking element through the airways of the individual *to the terminal bronchiole*." (emphasis added). The disclosure certainly supports inserting a blocking element through the airways of an individual, but it does not support inserting it into a terminal bronchiole. There is no mention in the specification of placing a blocking element or material in a terminal bronchiole.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27, 39, 41, 49 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Skupin (US Patent 5,250,286).

Regarding Claim 27, Skupin teaches a method of treating emphysema (col. 3, line 47) by providing a "blocking element" (an aerosol particle of approximately 5mm dispersed in the respiratory tract of a patient, see col. 8, lines 10-17) through the airways of the individual. Since the powder disperses through the respiratory tract, it is inherent that some particles will be "released" in the terminal bronchiole. If an aerosol particle is "released" in the terminal bronchiole, it is also inherent that the blocking element will prohibit air from flowing through the terminal bronchiole into the airspace as the patient inhales and isolates the airspace supplied by the terminal bronchiole so that

the airspace deflates over time as the air in the airspace becomes absorbed.
(Bronchioles are inherently about 3mm in diameter).

Regarding Claim 39, the claim is anticipated for the same reason as above noted with respect to claim 27 by a second aerosol particle blocking a second terminal bronchiole. Skupin's treatment uses many aerosol particles, so it is inherent that a second particle will block a second terminal bronchiole during the course of treatment with aerosol.

Regarding Claims 41 and 51, Skupin teaches treating emphysema (col. 3, line 47).

Regarding Claim 49, the claim is rejected for the same reason noted above with respect to claim 27.

Response to Arguments

7. Applicant's arguments with respect to claims 27 and 49 have been considered but are moot in view of the new ground(s) of rejection.

8. In response to the Applicant's interview summary filed on August 14, 2009, Examiner respectfully disagrees that the recited limitation of "inserting the blocking element through airways of the individual to the terminal bronchiole.." is supported by the specification. The second paragraph of the specification recites that emphysema is defined as an enlargement of air spaces distal to the terminal bronchioles. This only defines the disease, and not the method of treatment.

On page 4, lines 4-6, the specification details the treatment method as inserting an obturator in a bronchial tube. A "bronchial tube" is broader than a "terminal

bronchiole" – a "bronchial tube" can be any of the tubes branching from a bronchus, while a "terminal bronchiole" is the last portion of the nonrespiratory conducting airway. The two terms are not equivalent; thus, it is not clear that the specification supports "inserting the blocking element through airways of the individual to the terminal bronchiole."

Allowable Subject Matter

9. Claims 28-38 and 50 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ARUNDIPTA SHOME whose telephone number is (571)270-5539. The examiner can normally be reached on Monday through Friday 9:00am to 6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Arun Shome/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771